order to fraudulently increase the number of Serostim prescriptions written and paid for by consumers and third-party payors. Among other things, the Defendants and others unknown, distributed BIA medical devices and associated software to Serono's sales representative, and trained and supervised them in the presentation of these devices to purportedly measure body cell mass, diagnose AIDS wasting, and promote the sale of Serostim.

78. In or about September 1996, a representative of Serono traveled to Clinton Township, Michigan, and met with RJL, Liedtke, and others unknown regarding possible uses of the BIA and FNA software devices by Serono in marketing Serostim.

79. In or about October 1996, representatives of Serono met with Liedtke and employees of RJL and others unknown in Massachusetts regarding the sale and delivery of BIA and FNA software devices by RJL to Serono and others unknown.

80. In or about December 1996, Serono received in Massachusetts approximately 50 BIA devices, accompanied by approximately 50 FNA software devices that included the Z equation, manufactured by RJL and Liedtke and shipped from Michigan. Pursuant to directions and specifications from Serono, RJL and Liedtke affixed plates to the outside of these BIA devices bearing name "Serono."

81. Commencing in or about February 1997, and continuing thereafter, Serono provided the BIA devices and FNA software received from RJL and Liedtke to Serono's sales representatives and to others known and unknown to the United States Attorney for use in measuring body cell mass, diagnosing AIDS wasting in human who were potential candidates for receiving the drug, and promoting sales of Serostim.

82. Commencing in or about March 1997, and continuing thereafter, employees of RJL traveled from Michigan to Massachusetts and elsewhere, at Serono's

request, and provided training to Serono's sales representative in performing BIA tests on humans.

83. Commencing in 1997, and continuing thereafter, Serono's representatives performed, free of charge, BIA tests directly on AIDS patients in physician and medical clinic offices and at events sponsored by service organizations offering assistance to AIDS patients. Serono's sales representatives provided the BIA test results to doctors and patients and, in many instances, purported to interpret the test results for the purpose of diagnosing whether the patients were wasting and determining whether they needed Serostim.

84. Commencing in or about June 1997, and continuing thereafter, Serono forwarded to its sales representatives copies of various training materials prepared by RJL and by others for the purpose of training Serono sales representatives in performing BIA tests on humans and in interpreting BIA test results.

85. In or about June 1997, Serono obtained from RJL a "Body Composition Analysis Worksheet" and disseminated it to Serono's representatives for use in interpreting BIA tests and obtaining reimbursement for Serostim from third-party payors.

86. Commencing in 1999, and continuing thereafter, Serono required its sales representatives to submit bi-weekly reports to Serono's management showing how many BIA tests the sales representatives performed and how many prescriptions of Serostim were obtained as a result of those BIA tests.

87. Thereafter, Serono provided, free of charge, BIA medical devices and software devices to physicians and others involved in treating AIDS patients, and further arranged for the purchase, by physicians and others, of BIA and software devices at a reduced cost. Serono also provided training in performing and interpreting BIA tests to physicians and

others involved in treating AIDS patients, and arranged for such training to be provided by others.

88. Commencing in 1996, and continuing thereafter, Serono, RJL, and Liedtke promoted reliance upon BIA test results by third-party payors, for the purpose of determining whether a patient was suffering from AIDS wasting and whether to reimburse for Serostim prescriptions.

89. In or about August 1997, Serono executed a written agreement governing the sale of by RJL and Liedtke of BIA and computer software devices. Pursuant to this agreement, Serono and RJL agreed that RJL would provide "a specialized, private labeled model [BIA device] for Serono" that included, among other things," "R.J.L.'s Fluid & Nutrition Analysis Clinical Software Program for medical reimbursement," and further agreed to cooperate with RJL "for the development of new software and/or hardware for the diagnosis and monitoring of AIDS Associated Wasting and monitoring treatment with Serostim."

90. Commencing in or about August 1999, Serono collaborated with RJL and Liedtke and others unknown in the creation of the BIA computer software package known as "SomaScan." Serono knew and intended that the SomaScan software computed "ideal" body composition values by comparing the individual subject's BIA test results to a select portion of a database of humans derived form the NHANES database, and that the SomaScan software provided these "ideal" values as precise numerical amounts, rather than as ranges for these values. Serono expressly directed RJL and Liedtke to eliminate any standard deviation from the SomScan software in order to identify additional purported candidates for receiving Serostim and to increase sales of Serostim.

91. Commencing in or about August 1999, Serono received various versions of the SomaScan software from RJL, created copies of the computer software, and affixed labels to this software that identified it as SomaScan software and bore the name "Serono."

92. Commencing in or about September 1999, Serono disseminated the SomaScan software to its sales representatives and to others known and unknown to the United States Attorney for use in measuring body cell mass, diagnosing AIDS wasting in human who were potential candidates for receiving Serostim, and promoting sales of Serostim.

93. Commencing in or about September 1999, Serono prepared and disseminated training materials regarding the SomaScan software, provided training to sales representatives and to other unknown in the use of the software, and established a "Hotline" that users of the SomaScan software could telephone to obtain guidance in using the software.

94. Commencing in or about September 1999, RJL and Liedtke, acting at the direction of Serono, prepared and posted a website which provided information and training regarding the use of the SomaScan software.

95. Commencing in or about October 1999, and continuing thereafter, Serono initiated an assessment of the validity of the SomaScan software after receiving complaints that the SomaScan software was flawed and that BIA tests performed using the SomaScan software showed individuals to have AIDS wasting who were not in fact wasting.

96. Commencing in or about February 2000, Serono, RJL, Liedtke, and others unknown, evaluated the possible use by Serono of version of RJL computer software known as Cyprus. Pursuant to directions from Serono, RJL and Liedtke created the version of the Cyprus software known as Cyprus 1.2 Condensed for use by physicians and others unknown.

97. In or about September 2000, Serono decided to withdraw the SomaScan software from use by its representatives. In place of the SomaScan software, Serono disseminated the Cyprus 1.2 Condensed software to Serono sales representatives and others unknown for use in purportedly measuring body cell mass, diagnosing AIDS wasting in humans, and promoting sales of Serostim.

98. Commencing in or about September 2000, and continuing until at least January 2002, Serono disseminated the Cyprus 1.2 Condensed BIA software to others known and unknown to for use in purportedly measuring body cell mass and diagnosing AIDS wasting in humans who were potential candidates for receiving the drug, and promoting sales of Serostim.

99. Defendant's campaign of criminal fraud and deceit resulted in windfall revenues for Serono. Serono, S.A. announced in a January 18, 2000 news release that "Serostim further expanded its leadership in the treatment of AIDS wasting in the U.S. market, with sales rising 55.9% to $137.4 million from 88.2 million in 1998." What defendant did not disclose was that these revenues resulted from a course of deceptive and illegal conduct that resulted in millions of dollars of prescriptions of Serostim that were written and sold without medical necessity or scientifically valid proven effectiveness.

G. Defendants' Plan to Fraudulently Promote Serostim Through Payment of Kickbacks to Physicians

100. From in or about 1996 through in or about September 2000, Serono's Metabolic and Immune Therapy business unit (hereinafter "M&IT") was responsible for marketing and selling Serostim in the United States. Following a corporate reorganization in or about September 2000, the business unit responsible for selling Serostim in the United States was known as "Metabolic Endocrinology of North America" ("MENA").

101. In March 1999, the M&IT sales force was divided into six sales Regions each led by a Regional Director: the Northeast Region (Massachusetts, Maine, Connecticut, Vermont, New Jersey, parts of Pennsylvania and New York State); the New York Region (New York City and its environs); the Southeast Region (Florida, Louisiana, Mississippi, Alabama and Texas); the Central Region (Illinois, Wisconsin, Missouri, Arkansas, Oklahoma, Kentucky, Michigan, Minnesota, North Dakota, South Dakota, Nebraska, Iowa and Indiana); the Mid-Atlantic Region (Maryland, Delaware, Georgia, North Carolina, South Carolina, Ohio, West Virginia, and part of Pennsylvania); and the Western Region (California, Oregon, Washington, Arizona, and Colorado).

102. John Bruens (hereinafter referred to as "Bruens") held various positions in Serono. In 1999, defendant Bruens was the Vice-President of Marketing for M&IT working out of Serono headquarters in Massachusetts and reported directly to Executive X.

103. Mary Stewart (hereinafter referred to as "Stewart") held various positions in Serono. In 1999, Stewart was the Vice-President of Sales of M&IT working out of Serono headquarters in Massachusetts and reported directly to Executive X.

104. Melissa Vaughn (hereinafter referred to as "Vaughn") held various positions in Serono's M&IT business unit. In 1999, Vaughn was the Regional Director of Sales for the Southeast Region and reported directly to Stewart. As Regional Director of Sales for the Southeast Region, Vaughn supervised sales representatives (known within Serono as "clinical consultants") in Florida, Louisiana, Mississippi, Alabama and Texas.

105. Marc Sirockman (hereinafter referred to as "Sirockman") was employed by Serono's M&IT business unit in a variety of positions. In or about January 1999, Sirockman became Regional Director for the Northeast Region and reported directly to

defendant Stewart. As Regional Director of Sales for the Northeast Region, Sirockman supervised clinical consultants in Massachusetts, Maine, Connecticut, Vermont, New Jersey, parts of Pennsylvania and New York State.

106. At various times, Bruens, Stewart, Vaughn and Sirockman, along with others both known and unknown, including Adam Stupak, who was the Regional Director of Sales for the New York Region, were among top management responsible for sales and marketing of Serostim.

107. Prior to filing its two-count Information against Serono Laboratories, Inc., the United States Attorney for the District of Massachusetts filed indictments against Bruens, Stewart, Vaughn and Sirockman in the Untied States District Court, District of Massachusetts.

108. The United States Attorney also filed a three-count Information against Stupak, to which Stupak has pleaded guilty.

109. In the indictment, Drs. FL, P, DC, AC, O, G and W are each identified as physicians who provided care and treatment for patients who were HIV positive or suffering from AIDS. Drs. RL and P are identified in the indictment as located in and treated patients in Florida; Drs. CD and AC were located in and treated patients in New Jersey; and Drs. O, G and W were located in and treated patients in New York. Each of these physicians prescribed Serostim from time to time to patients.

110. During 1999, the top managers of Serono's M&IT business unit who were responsible for Serostim sales and marketing were Executive X and Bruens and Stewart.

111. In or about late 1998 or early 1999, Serono scheduled a National Sales Meeting to be held in Massachusetts from March 15-19, 1999, at which time representatives from various corporate business units of Serono, and Bruens and Stewart on behalf of the

M&IT unit, would be required to present sales information concerning the products being marketed by their respective corporate business units.

112. In February 1999, Bruens and Stewart were aware that the M&IT business unit was falling significantly short of its sales goals with respect to sales of Serostim.

113. The 3rd International Conference on Nutrition and HIV Infection was held in Cannes, France from April 22-25, 1999 (hereinafter referred to as the "Cannes Conference"). The Cannes Conference was organized to include new data on advances in the treatment of nutritional aspects of HIV disease, including but not limited to the effects of protease inhibitors on body composition, metabolism and hormone systems.

H. Defendants' Implementation of the Plan To Pay Physician Inducements

114. Commencing on or about March 1, 1999, and continuing thereafter until in or about December 1999, Serono, along with Bruens, Stewart, Vaughn, Sirockman Executive X, Stupak, and others unknown, knowingly and willfully combined, conspired, and agreed to offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to specific, identified physicians to induce them to refer individuals to pharmacies for the furnishing of the drug Serostim. The association of Serono, the Serono managers, and the targeted physicians, is known as the Physician Kickback Enterprise.

115. The purpose of the Physician Kickback Enterprise was to target physicians who were high prescribers of Serostim or who were generally regarded as "thought leaders" and to offer certain of these physicians financial incentives in order to obtain the number of prescriptions that would advance a sales goal of increasing sales of Serostim by $6,000,000, which was to be accomplished by offering an all-expenses paid trip for each physician and a guest to the Cannes Conference in return for the physicians writing additional prescriptions of Serostim.

116. To advance the purposes of the Physicians Kickback Enterprise, Executive X and Bruens and Stewart devised a plan called the "$6m-6 Day Plan," which had as an objective to target top prescribing Serostim physicians and top "thought leader" physicians in the AIDS/HIV medical community and then induce the targeted physicians to write more prescriptions by offering as an inducement an all-expenses paid trip to the Cannes Conference.

117. Pursuant to that Plan, Bruens and Stewart summoned the six Regional Directors of M&IT, including Stupak, Vaughn, and Sirockman, to an emergency meeting at the Boston Harbor Hotel on March 1, 1999. At this meeting, which included other M&IT personnel, Executive X, Bruens, and Stewart told the six Regional Directors that they were falling short of their sales goals for Serostim. Executive X, Bruens and Stewart also advised the Regional Directors that they needed to "dig their way out" of this fiscal crisis and informed the Regional Directors of the "$6m-6 Day Plan."

118. Although this target number of prescriptions per physician changed over time, the "$6m-6 Day Plan," as originally explained by Bruens and Stewart, would increase total sales of Serostim by more than $6,000,000 within six days.

119. To implement the plan, Bruens and Stewart required each Regional Director, including Stupak,Vaughn, and Sirockman, to report daily to Serono headquarters in Massachusetts the number of Serostim prescriptions that they obtained during the sales push, including those prescriptions obtained from the key physicians who were targeted and offered the opportunity to attend the Cannes Conference.

120. As a consequence of the plan, Serono, Bruens, Stewart, Vaughn and Sirockman and various others, including Adam Stupak, offered and caused to be offered to selected physicians the opportunity to attend the Cannes Conference with a guest with all

expenses paid by Serono in return for the physicians writing additional prescriptions of Serostim.

121. As part of the implementation of the plan, in exchange for the physicians' writing additional Serostim prescriptions, various co-conspirators and Bruens, Stewart, Vaughn, Sirockman, and others caused Serono to pay for the travel expenses of the physicians and their guests who attended the Cannes Conference.

122. In exchange for the physicians' Serostim's prescriptions, Serono, Bruens, Stewart, Vaughn, Sirockman, and others caused Serono to pay thousands of dollars for the hotel accommodations, meals, and entertainment for the physicians and their guests while they were at the Cannes Conference.

123. Further, Serono and various co-conspirators including Bruens, authorized and caused a variety of personal gifts to be provided to the physicians and their guests who attended the Cannes Conference.

124. After certain physicians rejected the Cannes offer, Serono and its employees advised certain of the physicians who had already been offered the all-expenses trip to the Cannes Conference that they would be asked to speak on behalf of Serono about the issues presented at the conference and about Serostim, and the physicians were paid separately for these speaking engagements.

I. Defendants' Payment of Inducements to Physicians to Prescribe Serostim

1. The Offer to Dr. RL

125. Between on or about March 1 and on or about March 3, 1999, various co-conspirators, including Serono, Bruens, Stewart and Vaughn, caused a co-conspirator who was a Serono clinical consultant to visit Dr. RL, a physician in Florida who treated HIV

positive and AIDS patients, and to offer Dr. RL the trip to the Cannes Conference in return for writing additional prescriptions of Serostim.

2. The Offer to Dr. P

126. Between on or March 1, 1999 and on or about March 3, 1999, various co-conspirators, including Serono, Bruens, Stewart and Vaughn, caused a co-conspirator who was a Serono clinical consultant to visit the office of Dr. P, a physician in Florida who treated HIV positive and AIDS patients, and to offer Dr. P the trip to the Cannes Conference in return for writing additional prescriptions of Serostim.

127. On or about March 13, 1999, defendant Vaughn advised Bruens that Dr. P would attend the Cannes Conference and would need business-class airline tickets.

128. On or about April 8, 1999, Bruens directed an employee in Norwell, Massachusetts, to charge $7,846.64 on a corporate credit card to cover the cost of Dr. P's round trip airfare, which had been booked by Serono's travel agency.

3. The Offer to Dr. DC

129. In or about March 1999, the exact dates being unknown, various co-conspirators including Serono, Bruens, Stewart and Sirockman, caused a co-conspirator who was a Serono clinical consultant to visit the office of Dr. DC, a physician in New Jersey who treated HIV positive and AIDS patients, and to offer Dr. DC the all-expenses paid trip to the Cannes Conference in return for gaining clinical experience with at least 30 Serostim patients before Dr. DC could attend the conference.

4. The Offer to Dr. AC

130. In or about March 1999, the exact dates being unknown, various co-conspirators, including Serono, Bruens and Stewart, caused Sirockman to contact Dr. AC, a physician in New Jersey who treated HIV positive and AIDS patients, and to offer to him the

all-expenses paid trip to the Cannes Conference in return for writing of additional prescriptions of Serostim.

131. On or about April 15, 1999, various co-conspirators, including Serono, Bruens, Stewart and Sirockman, caused Dr. AC to receive a check in the amount of $4,000 for airline tickets.

132. On or about April 25, 1999, Sirockman, using his corporate expense account, paid for Dr. AC's transportation in a private limo service for Dr. AC's return to his resident from an airport in New York after the Cannes Conference.

5. The Offer to Dr. O

133. Between on or about March 1, 1999 and on or about March 4, 1999, various co-conspirators, Serono, Bruens and Stewart, caused Adam Stupak to visit the office of Dr. O, a physician in New York City who treated HIV positive and AIDS patients, and to offer Dr. O the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.

6. The Offer to Dr. G

134. Between on or about March 1, 1999 and on or about March 4, 1999, various co-conspirators, including Serono, Bruens and Stewart, caused Adam Stupak to visit the office of Dr. G, a physician in New York City who treated HIV positive and AIDS patients, and to offer Dr. G the trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.

7. The Offer to Dr. W

135. Between on or about March 1, 1999 and on or about March 4, 1999, various co-conspirators, including Serono, Bruens and Stewart, caused Adam Stupak to visit the office of Dr. W, a physician in New York City who treated HIV positive and AIDS

patients, and to offer Dr. W the all-expenses paid trip to the Cannes Conference in return for his writing at least 10 additional prescriptions of Serostim.

136. On or about April 15, 1999, various co-conspirators, including Serono, Bruens and Stewart, and Adam Stupak, caused a $4,000 check for airline tickets to be issued to Dr. W, who had accepted the offer for the all-expenses paid trip to the Cannes Conference.

137. In or about March 15-19, 1999, during a presentation at Serono's National Sales meeting, Bruens announced the names of 10 physicians who were "US Invitees" to the Cannes Conference, including Dr. P in Florida; Dr. AC in New Jersey; and Drs. O, G and W in New York.

J. Defendants' Promotion of Inflated Dosages of Serostim

138. Although the recommended and most commonly prescribed dosage of Serostim was 6mg daily, Serono had learned through the experience of its sales representatives that a dose of 4mg taken every other day would generally produce the benefits sought by the 6mg daily Serostim therapy with greatly reduced or eliminated side-effects.

139. Upon information and belief, Serono sales representatives communicated their experience to Serono, but were instructed by Serono to continue to recommend 6mg daily as the optimal dosage for Serostim and to suggest prescriptions of anti-inflammatory drugs to deal with Serostim's side-effects.

140. In connection with receiving accelerated approval from the FDA to market Serostim, Serono represented that it would "further study the drug… to verify its clinical benefits including the determination of the optimal dose." Letter Thomas A. Lang, Serono's Vice President, regulatory affairs, to the FDA, dated June 27, 1996.

141. Serono however, never conducted, and indeed, consciously avoided conducting, the promised studies. Serono failed to conduct the additional studies because it

knew that such studies would result in a finding that effective Serostim therapy could be achieved through administering a dosage of Serostim that was both smaller and less frequently administered than the 6mg daily dosage.

142. If a study were to establish the optimal dosage for Serostim as a 4mg dose taken three to four times per week, then the impact on Serono revenues would be substantial. As only 12-16mg of Serostim would be required weekly, rather than the current 42mg, Serono's revenues would be, at the very least, cut in half as a result of Serono conducting the promised studies. Therefore, on information and belief, the effect of Serono's knowing failure to conduct the promised studies is to cause consumers and third-party payors to pay double, if not three to four times more than, the amount necessary for effective Serostim therapy.

K. Defendants' Off-Label Marketing of Serostim

143. In addition to its other efforts to fraudulently obtain payment from consumers and third-party payors, Serono also received payment for an unauthorized "open-label study." As a result, Serono engaged in off-label marketing.

144. Serono established what it called an "open-label study" to determine the effect of Serostim on lypodystrophy, a condition that occurs in HIV patients. At the time, Serono was in the midst of FDA trials attempting to obtain orphan drug status for Seroistim for the treatment of lypodystrophy.

145. Under the protocol established by Serono for the "open-label study," participating physicians were permitted to prescribe Serostim for up to a six month period for treatment of lypodystrophy. Third-party payors were billed for prescriptions of Serostim under the "open-label study."

146. Serono directed its sales force to inform physicians about this study, assist in establishing the criteria for the study, identifying potential participants, and monitoring the patients enrolled.

147. In fact, the study was *not approved* by the FDA for evaluation of Serostim in the treatment of lypodystrophy. Consequently, the physicians who participated were, in fact, prescribing Serostim for an unapproved and unrecognized off-label use because lypodystrophy was not an FDA-approved indication for the drug.

148. Many months after the representatives had marketed Serostim for use in treating lypodrostrophy and physicians had prescribed pursuant to the purported study, and the studies were terminated by order of Serono management.

L. Defendants' Other Drugs

149. The other drugs covered by this lawsuits are Cetrotide®, Crinone®, Gonal-F®, Fertinex®, Ovidrel®, Pergonal®, Profasi®, Rebif®, and Saizen®.

150. Serono has six recombinant products on the market in three core therapeutic areas: reproductive health, multiple sclerosis, and growth and metabolism. Recombinant technology allows the modification of cells or rapidly growing microorganisms (such as some mammalian cells, yeast or bacteria) by introducing into a segment of their DNA a gene enabling them to produce specific proteins. Serono's products include: Gonal-F ®- the first recombinant gonadotropin approved for treatment of infertility; Rebif ®– the first interferon for Multiple Sclerosis available at two dosages in a liquid pre-filled syringe, and the highest dose interferon beta available around the world; Saizen® – Serono's first recombinant drug to receive marketing approval, used for the treatment of growth disorders in children; and Serostim® – and injectable growth hormone.

151. Cetrotide® is a synthetic decapeptide with gonadotropin-releasing hormone antagonistic activity and is administered through injection.

152. Crinone® is a progesterone vaginal gel for use by infertile women and ministered through injection.

153. Fertinex® is used to stimulate the development of multiple follicules in ovulatory patients undergoing assisted reproductive technologies such as in vitro fertilization and is administered through injection.

154. Ovidrel® used in infertility treatment cycles to help follicles mature and to trigger the actual release of mature eggs from a woman's ovaries following treatment with products containing human follicle stimulating hormone and is administered through injection.

155. Pergonal® is a natural purified product extracted from the urine of post-menopausal women. It is administered by intramuscular injection. The hormones in Pergonal stimulate the ovaries to develop mature follicles, which contain eggs.

156. Profasi® is a purified preparation of a natural hormone called human chorionic gonadotropin that is used with fertility treatment in women, usually with other fertility medications, to assist eggs with breaking through the follicle, or ovulate. It is administered through injection.

157. From 1999 through the present, defendants created and implemented a fraudulent marketing and sales scheme to substantially increase the sales of these drugs manufactured and reap unlawful profits at the expense of Medicare patients, healthcare insurers, consumers and others. Defendants systematically, among themselves and with other entities and individuals, created a pervasive, illegal system to cause individual patients and their insurers to overpay substantial amounts of money for the specific purpose of

increasing the market share of these drugs and maximizing their profit at the expense of Plaintiff and the Class.

158. The improper marketing and sales practices include, *inter alia*: (a) deliberately overstating the published average wholesale price ("AWP") for these drugs — the rate upon which Medicare reimbursement (and Medicare beneficiaries co-payments) as well as many other insurers' payments are set — so that Plaintiff and the Class pay an artificially inflated amount of money for Serono drugs; (b) providing free samples and financial assistance to medical providers and instructing them, with the intent, that they could and should unlawfully bill Medicare, private insurers and individual patients for the free samples or without reflecting the impact of the financial assistance on average wholesale price; (c) providing other unlawful financial inducements and hidden price discounts without reflecting the impact of those discounts on average wholesale price; and (d) actively concealing, and causing others to conceal, information about the true price being charged for Serono drugs.

M. The Average Wholesale Price

159. Manufacturers, including Serono, have caused to be published an average wholesale price (or "AWP") for their prescription pharmaceuticals. The average wholesale price or AWP is a price used for invoices between drug wholesalers and pharmacies (or other appropriate drug dispensers, such as doctors for physician-administered drugs) and is typically used as a benchmark for the reimbursement by end-payors for the dispensers' (*e.g.*, retail pharmacies or doctors) acquisition of the drug product. Historically, the AWP is set directly or indirectly by the drug manufacturer, with an effective date and remains in effect until a change in price is published.

160. Wholesale Acquisition Cost ("WAC") represents a list price from manufacturer to wholesaler. AWP represents a list price from wholesaler to dispenser (*e.g.*, pharmacy, physician, hospital, or other provider).

N. The Private End-Payors for Prescription Drugs

161. Private payors for prescription drugs include drug benefit plan sponsors and consumers. The drug benefit plan sponsors (who pay for part or all of the cost of prescription drugs for their covered beneficiaries) include self-insured employers, health and welfare plans, health insurers and managed care organizations (MCOs). Most of these plan sponsors reimburse retailers (for retailers' drug purchase costs) through pharmacy benefit administrators (either health plans or pharmacy benefit management companies) who negotiate discounts with retail pharmacies and rebates from drug manufacturers. The vast majority of such purchases are for out-patient drugs that are self-administered, *i.e.*, drugs distributed through the retail distribution channel.

O. End Payors Drug Reimbursements Are AWP-Based

162. Although retail pharmacies *purchase* pharmaceutical products based upon pricing formulae that employ the WAC, retail pharmacies *get paid* (*i.e.* receive reimbursement) from plan sponsors and consumers based upon an AWP reimbursement formula plus a dispensing fee. This is a fundamental anomaly of the retail distribution channel for drug products – that retail pharmacies' *purchases* are based on prices pegged to the published WAC, but retail pharmacies' *reimbursements* or charges are based on the published AWP.

163. Health plans typically contract with intermediaries called pharmacy benefit managers ("PBMs") to negotiate prices with manufacturers and retail pharmacies and thereafter adjudicate the numerous transactions that occur during administration of a plan.

Although the PBM negotiates prices and adjudicates claims, the plan sponsor (*i.e.*, insurer, self-insured employee, health and welfare plan) remains at risk for the charges paid to retail pharmacies and mail orders. In the contracts between PBMs and plan sponsors, the retail pharmacies drug ingredient costs for brand-name drugs are reimbursed at the AWP less a certain percentage, or "discount."

164. Brand drug reimbursement for retail pharmacy ingredient cost contained in the contracts between PBMs and plan sponsors, and PBMs to pharmacies, use an AWP-based reimbursement structure. For example, since 2002, Express Scripts' standard form contract has expressly stated that its reimbursement formula is based on AWP from the "current information provided to ESI by drug pricing services such as First Data Bank...." Similarly, Caremark's website states: "For both brand and generic drugs, the pricing formula at retail and mail is based on the discounted Average Wholesale Price (AWP) as reported by First Data. Caremark loads First Data's updated data into the system on a daily basis." Other PBMs expressly utilize First Data's published AWPs as the source of AWP pricing to be utilized in payment.

165. The AWP-based reimbursement benchmark for private payments to the retail class of pharmaceutical trade has long been acknowledged. Most recently, at a hearing on December 7, 2004, before the United States House of Representatives Committee on Energy and Commerce, a former Senior Vice President of Aventis Pharmaceuticals, testified that "AWP has been codified as the benchmark price, by statute and regulations, in the public sector and by contract in the private sector."

166. In addition to affecting the magnitude of plan sponsors' branded drug reimbursement to retail pharmacies for drug ingredient costs, the private sector AWP-based

system also affects consumers. There are primarily two types of consumer: those who have some type of pharmacy benefit coverage and pay a portion of the cost of a drug (co-payment, co-insurance, deductible), and those who have no coverage and pay the entire cost of the prescription drug at the retail pharmacy.

167. Consumers that pay "co-insurance" are at risk for the delivery of their drug benefit ratably with their insurer; to the extent that the overall reimbursement amount unlawfully is inflated, the consumer group is co-insurance is proportionally injured.

168. Consumers that do not have insurance are sometimes referred to as "cash-paying consumers," and they include many seniors who are eligible for Medicare. Recent estimates suggest that these consumers (*i.e.*, Medicare-eligible seniors who have no prescription drug coverage or who are covered by traditional indemnity plans and must therefore pay the full amount prior to reimbursement), amount to more than one-fifth of the private prescription drug expenditures at retail pharmacies. Most retail pharmacies based their price to cash payors on formulae tied to the AWP.

169. Consumers who have insurance coverage and those who are eligible for government programs (such as Medicaid) typically pay less than consumers who do not have such coverage. Uninsured consumers, or cash payors, are disproportionately elderly and poor consumers.

170. In summary, thousands of pharmaceutical reimbursement contracts are based on AWP minus a specified discount. As a result, a leading expert on pharmaceutical pricing has concluded that "AWP is the glue that binds the system of pharmaceutical reimbursement rates. All or predominantly all, reimbursement rates for pharmaceuticals

purchased under public sector and private drug benefit insurance plans are negotiated based upon AWP and discounts from AWP."

P. Medicaid Drug Reimbursements Are AWP-Based

171. Public purchases for prescription drugs provide a variety of programs for low-income and elderly patients, veterans, members of armed services, and federal, state and local government employees. While public purchaser programs are not directly at issue in this case, the significant reliance on those systems of AWP-based reimbursement underscores the ambiguity and magnitude of reliance on the AWP-based reimbursement system to pay for dispensers' ingredient costs for branded pharmaceutical products.

172. Medicaid has the most significant impact on prescription drug pricing for out patient drugs. The Medicaid program, jointly financed through federal and state funds, is designed to aid low-income people and the disabled, and covers about 40 million individuals. Between 1997 and 2002, Medicaid expenditures for prescription drugs in the fee-for-service part of the program increased at an average annual rate of 18%, going from $10.2 billion to $23.4 billion. (While these are significant sums, they amount to less than 10% of the overall annual prescription drug expenditure).

173. Medicaid's reimbursement system relies upon the published list prices of drugs (which are largely directly set by manufacturers) to determine pharmacies' reimbursement. States reimburse pharmacies using formulas that are typically based on the average wholesale price or AWP of a drug. For example, a state might reimburse a pharmacy 85% to 90% of the average wholesale price of a drug plus a fixed dollar amount of $3 to $5 (as dispensing fee) to cover the pharmacy's other costs.

Q. Medicare Drug Reimbursements Were AWP-Based

174. The other significant public purchaser for prescription drugs is the federal Medicare program.

175. Until recently, the Medicare Program generally did not cover the cost of out-patient prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including indictable administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B.

176. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable.

177. Some Medicare beneficiaries are able to purchase private Medigap insurance, which covers, among other things, all or part of the 20% co-payment for Covered Drugs.

178. For many years up to and through 1997, Medicare's reimbursement system for the relatively narrow band of physician-administered drugs sought to estimate providers acquisition costs by pegging reimbursement to either the estimated acquisition costs or to the national average wholesale price sale price. In practice, carriers that administered the Medicare program reimbursed physicians and clinics for physician-administered drugs covered by Medicare on the basis of the published wholesale price or AWP.

179. Beginning in 1998, Medicare's practice of reimbursing based upon the published AWP was codified by statue and implemented by regulation. Beginning in 1998 and until recently, Medicare reimbursed for drugs and biologicals under its program of the reimbursing physician administered drugs based upon 95% of the published average wholesale price.

180. At the end of 2003, Congress enacted the Medicare Modernization Act. Among other things, that changed the AWP-based reimbursement system for Medicare to a system based upon each manufacturers' actual calculation for the average sales price for each drug or biological covered by the program. Interim rules transitioned the AWP-based system with modifications to the percentage off of AWP. Beginning in 2004, Medicare has been transitioning to the ASP-based reimbursement system.

181. In summary, the two largest public purchaser programs for prescription pharmaceuticals – Medicaid and Medicare – historically relied upon published average wholesale prices as the fundamental basis upon which to reimburse for branded drug ingredient costs incurred by dispensers (retail pharmacies for Medicaid, and medical providers in the Medicare area).

R. Private and Public End Payors Rely on Published Drug Pricing Compendia

182. The private (and public) pharmaceutical reimbursement systems have at their core critical dependence upon accurate and timely publication of the current AWP for every active formulation of drugs dispensed by retail pharmacies in the country. Given the breath of this dependence (private insurance systems covering more than 200 million lives as well as millions of cash payors) given the healthcare system's growing reliance on pharmaceutical products as a treatment of first resort, and given the scores of thousands of available drugs on the market, the private (and public) reimbursement systems for

pharmaceuticals depend on the honesty and integrity of the AWP and WAC data provided by drug manufacturers. The reimbursement systems (including the plan sponsors and consumers who reimburse drug dispenser costs) also rely upon the accuracy and integrity of the pharmaceutical pricing publishers to accurately and fairly publish AWPs and WACs for NDCs.

183. Several pharmaceutical industry compendia periodically publish the AWPs for active NDCs in the United States. Generally these publications are available in either hard copy format or in electronic media.

184. Generally speaking, the two printed compendia include Drug Topics Red Book (the "Red Book") (published by Thompson Healthcare) and American Druggist First Data Bank Annual Director of Pharmaceuticals and Essential Director of Pharmaceuticals (the "Blue Book") (which for several years has been defunct). While the Red Book is used to determine published AWPs (primarily for physician-administered drugs), and while certain limited electronic information is available regarding Red Book published prices, the Red Book remains primarily an annual printed publication with periodic printed updates.

185. In periodically announcing the AWP for each drug, publishers generally report prices that are supplied to them by manufacturers for their respective drugs. For instance, the forward to the 1999 edition of the Red Book states that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the Red Book, stated that Redbook only publishes prices that are faxed directly from the manufacturer.

S. Accuracy of AWPs

186. The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

187. And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and